

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

BARBARA A. LUSCH,

Plaintiff,

v.

MATRIX INITIATIVES, INC., a Delaware
Corporation; and ZICAM LLC, an Arizona
Limited Liability Company,

Defendants.

Civil No. 05-292-HA

OPINION AND ORDER

HAGGERTY, Chief Judge:

Plaintiff Barbara Lusch filed suit against defendants Matrixx Initiatives, Inc. and Zicam, LLC (defendants), alleging that Zicam No-Drip Liquid Nasal Gel Cold Remedy (Zicam) distorted and substantially diminished her sense of smell. On May 15, 2006, defendants filed a

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Motion for Summary Judgment [39] and two motions to exclude expert testimony. The first is a Motion to Exclude the Expert Report and Testimony of Bruce W. Jafek, M.D., and Miriam R. Linschoten, Ph.D. [44] and the second is a Motion to Exclude the Expert Report and Testimony of Edsel U. Kim, M.D., and Allen M. Seiden, M.D. [45]. The court completed oral argument on February 27, 2007, and took the matter under advisement at that time. For the following reasons, defendants' motions are GRANTED.

FACTUAL BACKGROUND

Zicam is a homeopathic cold remedy intended to place zinc in direct contact with the nasal epithelial membrane. The active ingredient in Zicam is zinc gluconate, which is supposed to reduce the length and severity of a cold. Zicam gel is delivered to the nasal membrane by a pump. The manufacturer's directions direct that the applicator tip should be placed approximately one-eighth of an inch past the nasal opening, with the nozzle angled slightly outward. The user is directed to pump the applicator once in each nostril. Finally, to avoid irritation, the user is directed not to "sniff up" the gel.

Plaintiff is a professional jazz singer who resides in Portland, Oregon. Plaintiff testified that she first used Zicam in February 2003, and first purchased the pump spray version in early 2003. Plaintiff testified that she used the pump as directed..

In November 2003, plaintiff was diagnosed with sinusitis, which was resolved by a tooth extraction, on the advice of Dr. Edsel Kim, a board-certified otolaryngologist. According to plaintiff, she experienced no rhinitis, sinusitis, upper respiratory infection, or any cold symptoms for the rest of December 2003 and through January and February 2004. Dr. Kim testified that

plaintiff did not have a sinus infection, rhinitis, or an upper respiratory infection during this period.

On February 24, 2004, worried that she had a cold coming on, plaintiff used Zicam. Plaintiff testified that she believes she used the product as directed that time, but cannot remember if she sniffed it up or not. She claims when she used Zicam she experienced a temporary burning sensation in her nose. The next morning, she testified that her sense of smell was distorted. Plaintiff continued to notice "irritating" smells, but plaintiff did not link her Zicam use with her distorted sense of smell. Plaintiff did not develop a cold after taking the Zicam on February 24.

Plaintiff saw Dr. Kim on March 31, 2004 after experiencing severely diminished and distorted smell for approximately a month. Dr. Kim found no signs of sinusitis, and preliminarily diagnosed plaintiff with parosmia, a condition in which a patient can smell some scents but others are distorted. Dr. Kim ordered an MRI to determine if the smell loss was associated with a mass or infection in the skull base; the MRI was negative. Plaintiff never mentioned her use of Zicam to Dr. Kim. Dr. Kim prescribed steroids for plaintiff, but this treatment was ineffective.

Plaintiff began researching her condition on the Internet and found reports of Zicam-induced smell loss. After informing Dr. Kim of this, Dr. Kim asked plaintiff to complete a smell loss test. Plaintiff's score placed her at "severe microsmia." Dr. Kim saw plaintiff again on May 24, 2004 and diagnosed her with "dysosmia," a distorted detection of the sense of smell.

In January 2005, plaintiff filed this action, alleging that Zicam caused her loss of smell.

STANDARDS

A. Rule 702 Scientific Evidence

Scientific evidence is admitted pursuant to Federal Rule of Evidence 702, which provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 587-89 (*Daubert I*), the Supreme Court held that Rule 702 displaced the prior "general acceptance" test. Thus, the district court acts as a gatekeeper, excluding bad science that does not carry sufficient indicia of reliability for admission under Rule 702. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316-17 (9th Cir. 1995) (*Daubert II*). This is accomplished through a preliminary determination that the proffered evidence is both relevant and reliable. *Daubert I*, 509 U.S. at 589-92.

Scientific evidence is reliable if it is based on an assertion that is grounded in methods of science—the focus is on principles and methodology, not conclusions. *Id.* at 595-96. The Supreme Court listed four non-exclusive factors for consideration in the reliability analysis: (1) whether the scientific theory or technique "can be (and has been) tested;" (2) "whether the theory or technique has been subjected to peer review and publication;" (3) whether a particular technique has a "known or potential rate of error;" and (4) whether the theory or technique is generally accepted in the relevant scientific community. *Id.* at 593-94. In *Daubert II* the Ninth

Circuit noted that a "very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." 43 F.3d at 1317. The *Daubert* inquiry, however, is "a flexible one," and must be "tied to the facts of a particular case." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999).

B. Summary Judgment

A party is entitled to summary judgment if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c); see *Bahn v. NME Hosps., Inc.*, 929 F.2d 1404, 1409 (9th Cir. 1991). The moving party carries the initial burden of proof and meets this burden by identifying portions of the record on file that demonstrate the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986). Once the initial burden is satisfied, the burden shifts to the non-moving party to demonstrate through the production of probative evidence that there remains an issue of fact to be tried. *Id.*

The court must view the evidence in the light most favorable to the non-moving party. *Fairbank v. Wunderman Cato Johnson*, 212 F.3d 528, 531 (9th Cir. 2000) (citations omitted). All reasonable doubt as to the existence of a genuine issue of fact should be resolved against the moving party. *MetroPCS, Inc. v. City and County of San Francisco*, 400 F.3d 715, 720 (9th Cir. 2005). Where different ultimate inferences may be drawn, summary judgment is inappropriate. *Sankovich v. Life Ins. Co.*, 638 F.2d 136, 140 (9th Cir. 1981).

Deference to the non-moving party does have some limits. The non-moving party "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). "The mere existence of a scintilla of evidence in support of the [non-moving party's] position will be insufficient." *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 252 (1986). Therefore, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quotation omitted).

ANALYSIS

A. Motions to Exclude Experts

Defendants filed two motions to exclude plaintiff's four causation experts under Rule 702. The first motion seeks to exclude causation testimony of Dr. Jafek and Dr. Linschoten, and the second seeks to similarly exclude testimony of Dr. Kim and Dr. Seiden.

1. Dr. Jafek

To prove that Zicam caused her smell loss, plaintiff offers the expert testimony of Dr. Jafek, a professor of otolaryngology at the University of Colorado School of Medicine. Defendants move to exclude Dr. Jafek's testimony under Rule 702. Defendants do not challenge Dr. Jafek's credentials as a physician, but whether he has faithfully applied the scientific method in his analysis of plaintiff's smell loss.

Dr. Jafek opines that Zicam can cause smell loss and that it did cause plaintiff's smell loss. His opinion is predicated on three main findings: (1) when the pump is actuated, Zicam can reach the sensitive smell tissue called the olfactory epithelium; (2) Zicam is toxic to, or damages,

the olfactory epithelial tissue; and (3) Zicam is delivered in a dose sufficient enough to permanently damage olfactory epithelial tissue. From these findings, Dr. Jafek opines that Zicam caused plaintiff's smell loss.

The court first finds Dr. Jafek's causation opinion is inadmissible because there is no reasonable scientific evidence that Zicam actually reaches the olfactory epithelium. Dr. Jafek conceded that Zicam will not reach the olfactory epithelial if the gel is sprayed laterally toward the nasal wall, as the Zicam directions counsel.

Dr. Jafek maintains, however, that it is possible for Zicam to reach the olfactory epithelium if squirted directly up the nose. Dr. Jafek bases his conclusion on the fact that when used with a nasal pump, Zicam squirts four to ten feet in the air. Dr. Jafek also conducted tests showing that the pathway from the outer opening of the nose to the olfactory epithelium is a "straight shot" in most patients. Dr. Jafek conducted tests in March 2005 on human cadavers that were sectioned through the septum. The septum was removed and replaced with a pane of glass allowing direct observation of the nose. Dr. Jafek sprayed Zicam straight along the pathway from the external opening of the nose, over the middle turbinate, to the olfactory cleft and olfactory epithelium. Dr. Jafek observed that the Zicam lodged in the olfactory cleft, covering the region of the olfactory epithelium.

Dr. Jafek's opinion that the Zicam will reach the olfactory epithelium rests on experiments in which he aimed the Zicam straight into the nose rather than laterally as the directions indicate. Thus, these experiments do not support Dr. Jafek's opinion as they are not

relevant to the issue in this case, i.e., whether Zicam actually reached plaintiff's olfactory epithelium when used as directed. *See Kumho*, 526 U.S. at 152 (there must be "a valid . . . connection to the pertinent inquiry as a precondition to admissibility"). Further, these experiments were also conducted post-litigation, an indicator of unreliability. *See* Advisory Committee Notes, Fed. R. Evid. 702.

Second, the court finds Dr. Jafek's causation opinion is inadmissible because there is no reasonable scientific evidence that Zicam is toxic to the olfactory epithelial tissue. Dr. Jafek opines that the zinc ions in Zicam are toxic to the epithelial tissue. He relies on several studies and his own case reports to support his finding, which defendants argue do not meet the standards necessary to establish scientific reliability.

Dr. Jafek relies largely on his interpretation of polio prevention experiments performed in the 1930's and 1940's with zinc sulfate. He also relies on behavioral studies in animals exposed to zinc sulfate. Defendants contend that the reliance on the polio literature is not scientifically valid because of the different methods and doses of exposure between those experiments and the circumstances of Zicam use. Defendants also argue that Dr. Jafek has failed to show that the behavioral studies in animals exposed to zinc sulfate support an opinion that Zicam causes smell loss in humans as they involved zinc sulfate, not zinc gluconate as in Zicam, and they involved different species with different olfactory systems and concentrations of zinc higher than those in Zicam.

Dr. Jafek's analogy between zinc sulfate and zinc gluconate is an unjustifiable extrapolation from an accepted premise to an unfounded conclusion. *See* Advisory Committee Notes, Fed. R. Evid. 702 (noting that whether an expert has justifiably extrapolated from a known premise to the conclusion is an important consideration in the *Daubert* analysis). Dr. Jafek has failed to show that the differences in chemical structures between the two compounds did not make a difference; instead Dr. Jafek merely extrapolated from an accepted premise (that zinc sulfate is toxic to the olfactory epithelium) to an unfounded conclusion (that the zinc gluconate in a dose of Zicam is toxic to the olfactory epithelium).

Third, Dr. Jafek's causation opinion fails because there is no reasonable scientific evidence that Zicam is delivered in a dose sufficient enough to permanently damage olfactory epithelial tissue. Defendants contend that Dr. Jafek has failed to offer sufficient evidence as to how much Zicam or zinc gluconate is needed to produce permanent anosmia (the dose-response relationship). Defendants also note that Dr. Jafek's opinion on toxic dose is unreliable because it was made during the course of litigation, not prior to forming and stating his opinion. *See* Advisory Committee Notes, Fed. R. Evid. 702.

Dr. Jafek relies on the animal studies, which explain how much zinc ion is toxic to mice, to conclude at what levels Zicam is toxic to humans. Dr. Jafek extrapolates that Zicam contains a toxic amount of zinc ions by comparing the size of smell tissue in the mice used in the study with the size of the smell tissue in humans. As discussed above, Dr. Jafek fails to explain and demonstrate why extrapolation in this instance is scientifically proper. In short, Dr. Jafek's

conclusion that a toxic dose of Zicam reaches the olfactory epithelium is not scientifically reliable. *See McLain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1241-42 (11th Cir. 2005) ("The expert who avoids or neglects to address the [dose-reponse relationship] without justification casts suspicion on the reliability of his methodology.").

Finally, Dr. Jafek opines that the plaintiff's use of Zicam caused her smell loss. He posits that Zicam delivered zinc to the olfactory epithelium, that this level of zinc was toxic to the olfactory epithelium, and this toxic dose which caused plaintiff's permanent loss of smell. As discussed above, Dr. Jafek has failed to show that when properly used Zicam can deliver zinc to the olfactory epithelium, thus he is unable to show that zinc had a toxic effect on plaintiff's olfactory epithelium. Consequently, he cannot show that intranasal application of Zicam caused plaintiff's loss of smell. Therefore, this court finds that Dr. Jafek's opinion that plaintiff's use of Zicam caused her smell loss is unreliable and therefore inadmissible under Rule 702.

2. Dr. Linschoten

Plaintiff offers Dr. Linschoten to testify on matters of specific and general causation related to Zicam and smell loss. Plaintiff asserts that Dr. Linschoten should be allowed to testify that Zicam can cause smell dysfunction and did cause smell dysfunction in plaintiff. Defendants argue that Dr. Linschoten's opinions are based on the same faulty science as Dr. Jafek's, and should therefore be similarly excluded. Defendants also challenge Dr. Linschoten's qualifications, noting that she is not a medical doctor and is therefore unqualified to give medical causation testimony.

Dr. Linschoten opines that Zicam can cause smell loss, and did cause smell loss in plaintiff. In reaching these conclusions Dr. Linschoten relies, however, on the same scientifically unreliable evidence created by, and relied upon, by Dr. Jafek. For the same reasons given above, Dr. Linschoten's opinions as to general and specific causation in this case are similarly inadmissible.

In light of the court's finding that Dr. Linschoten's conclusions are scientifically unreliable, the court need not reach whether Dr. Linschoten would be precluded from giving medical causation testimony based on her lack of qualifications as a medical doctor.

Accordingly, this court finds that Dr. Linschoten's opinion that plaintiff's use of Zicam caused her smell loss is unreliable and therefore inadmissible under Rule 702.

3. Dr. Kim

As plaintiff's treating otolaryngologist, Dr. Kim was the first doctor to diagnose plaintiff's smell loss. Plaintiff offers Dr. Kim to opine that to a reasonable degree of medical certainty, plaintiff's use of Zicam directly and proximately caused plaintiff's smell loss. Defendants argue that Dr. Kim's opinion as to medical causation is inadmissible because he relies on the same faulty science as Drs. Jafek and Linschoten.

In reaching this conclusion, Dr. Kim relies on his personal medical care of plaintiff, plaintiff's medical records, her smell test results, literature regarding intranasal zinc application and anosmia in humans, including the research done by Drs. Jafek and Linschoten

Dr. Jafek's research and evidence as to general causation (that Zicam causes smell loss), as explained above, lacks a reliable scientific basis. As plaintiff's treating physician, Dr. Kim may give expert testimony as to plaintiff's medical history, her smell test results, and his examination and treatment of plaintiff, but, without a reliable opinion on general causation, Dr. Kim cannot testify as to Zicam causing plaintiff's smell loss.

4. Dr. Seiden

Plaintiff offers Dr. Seiden for his opinion that Zicam caused plaintiff's smell loss. Dr. Seiden is a full professor and board-certified otolaryngologist at the University of Cincinnati. Defendants argue, again, that Dr. Seiden's opinions are based on the conclusions of Dr. Jafek, which the court has found are not scientifically valid.

Dr. Seiden's opinion that Zicam caused plaintiff's smell loss is based on his findings that (1) Zicam can reach the olfactory epithelium, and (2) that the zinc ions in Zicam are toxic and can cause smell loss. Dr. Seiden also opines that no other typical causes of anosmia caused plaintiff's smell loss. In support of his opinions, Dr. Seiden relies on plaintiff's medical records, her deposition, her smell test results, the literature on intranasal zinc application and smell loss, research done by Drs. Jafek and Linschoten, as well as several other studies and smell loss patients he has seen.

As explained above, there is no reasonable scientific evidence that Zicam can reach the olfactory epithelium or that Zicam is toxic to the olfactory epithelium. Dr. Seiden's reliance on additional sources to conclude that Zicam caused plaintiff's smell loss does not overcome the

basic problems with the underlying scientific conclusions. To be scientifically valid, a causation opinion must be predicated on reliable scientific evidence: in this case, that use of Zicam causes delivery of a sufficient dose of zinc gluconate to the epithelial tissue to cause smell loss. Dr. Seiden has not published, or relied, on any study that reliably establishes the dose-response relationship.

Accordingly, this court finds that Dr. Seiden's opinion that plaintiff's use of Zicam caused her smell loss is unreliable and therefore inadmissible under Rule 702.

Accordingly, defendants' motions to exclude expert causation testimony by Drs. Jafek and Linschoten [44] and Drs. Kim and Seiden [45] are GRANTED.

B. Motion for Summary Judgment

Defendants' motion for summary judgment argues that because the causation opinions of plaintiff's experts are unreliable and therefore inadmissible, plaintiff cannot demonstrate that Zicam caused her permanent anosmia. Defendants contend that because the issues in this case are complex and beyond the understanding of lay jurors, plaintiff will need to put forth expert opinions and testimony to support her claims. The court agrees.

Without admissible expert opinions or testimony linking plaintiff's use of Zicam with her loss of smell, plaintiff is unable to show causation. In *Claar v. Burlington Northern Railroad Co.*, 29 F.3d 499, 504 (9th Cir. 1994), the Ninth Circuit held that plaintiffs were required to produce expert testimony to show a casual link between plaintiffs' exposure to chemical and their alleged ailments. By failing to do so, plaintiffs could not prove a necessary element of their

claims, and summary judgment in favor of defendant was appropriate. Here, without expert testimony, plaintiff is similarly unable to create a genuine issue of material fact as to causation, and therefore summary judgment in favor of defendants is appropriate.

Accordingly, defendants' Motion for Summary Judgment [39] is GRANTED.

CONCLUSION

For the reasons stated above, defendants' Motion to Exclude the Expert Report and Testimony of Bruce W. Jafek, M.D., and Miriam R. Linschoten, Ph.D. [44] is GRANTED and defendants' Motion to Exclude the Expert Report and Testimony of Edsel U. Kim, M.D., and Allen M. Seiden, M.D. [45] is GRANTED. Because plaintiff cannot prove causation without expert testimony, defendants' Motion for Summary Judgment [39] is GRANTED.

IT IS SO ORDERED.

Dated this 25 day of September, 2007

/s/ Ancer L. Haggerty

Ancer L. Haggerty
United States District Judge